

## **REMARKS**

### **Status of the Claims**

This paper amends claims 4, 25, and 26 and adds new claims 27-38. After the amendments set forth above are entered, claims 4 and 25-38 are pending and under examination.

### **Support for Amendments**

Support for the addition of the term “antibody” in claim 4 is found in the specification at page 1, lines 30-31. Support for the term “pellet” is found in claim 4 and the specification at page 2, lines 28-31. A skilled artisan immediately recognizes this method is an organic solvent extraction wherein the upper and medial layers are the aqueous phase, the organic phase is “spilled,” and “the rest of the material” is the solid matter which forms a pellet at the bottom of the centrifuge vessel. Support for new claims 27 and 28 is found in claim 4 as originally filed and in the specification at page 2, line 24 through page 3, line 10. Support for new claims 29-38 are found in the claims as originally filed and in the specification at page 1, lines 7-15, page 2, line 23 through page 3, line 10, and at page 3, lines 15-18. The remainder of the amendments are minor in nature and made for purposes of clarity. These amendments add no new matter.

### **Objections**

The Examiner objects to claim 26 for failure to use the active voice. Claim 26 is amended to address this objection and this objection may now be withdrawn.

### **Rejection under 35 U.S.C. § 112, first paragraph**

Claims 4 and 25-26 stand rejected for lack of enablement. The Examiner alleges that practicing the claimed invention would require undue experimentation and that the claims, in view of the specification, fail to satisfy the legal standard of enablement set forth by the Wands court. In re Wands, 858 F.2d, 731, 8 USPQ2d 1400 (Fed. Cir. 1988). Applicant respectfully traverses this rejection.

The Wands analysis for enablement is not a rigid set of tests, each having only a binary outcome. Rather, the analysis is a balancing test in which all of the facts and circumstances are viewed together. As noted by the Examiner, the Wands court states:

Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.

Id. at 737; Office Action mailed October 25, 2006, at p. 3 (emphasis added).

Contrary to the requirements of Wands, the Examiner performed an incomplete analysis and omitted discussion of those factors that are highly favorable to the Applicant. The Examiner focused solely on factors 3, 5, 6, and 7, state of the prior art, level of predictability in the art, and existence of working examples, respectively, to the exclusion of all others. See, Office Action at page 4. Applicant respectfully submits that a complete analysis of the Wands factors, in view of the current amendments, compels withdrawal of this rejection. Applicant's analysis follows.

1) Breadth of Claims: The claimed invention is narrow in breadth which favors enablement. The claims are limited to a method of isolated an antibody from colostrum and the claimed method requires several specific analytical steps including specific requirements for extraction using organic solvents and incubation times.

2) Nature of the Invention: The invention relates to the purification of an antibody from colostrum. It is well-known that colostrum contains high levels of maternal antibodies and the prior art is replete with examples of antibody purification techniques. This factor favors a finding of enablement.

3) State of the Prior Art: In asserting this rejection, the Examiner characterizes this factor incorrectly and too narrowly. The Examiner asserts that the prior art does not disclose or suggest the claimed method and concludes, therefore, that the method is not enabled by the prior art.

Applicant respectfully disagrees with this analysis because the Examiner is implying that only prior art that anticipates (or renders obvious) the claimed invention is useful to support an enabling disclosure. This is clearly not the law. The prior art may be supportive on the issue of enablement if it provides instruction that is useful to the artisan in performing the claimed method. In the instant case, antibody purification techniques and characteristics are well known in the art, as is the macromolecular composition of colostrum. Thus, the prior art provides the artisan with ample guidance and information relevant to the claimed method. This factor favors enablement.

4) Relative Skill of Those in the Art: Antibody purification is typically performed by Masters- or Doctorate-level scientists or highly trained laboratory technicians who specialize in biomedical research. In view of the high skill level in the relevant art, this fact favors enablement.

5) The Predictability or Unpredictability of the Art: The Examiner asserts that it is not known in the art whether an anti-tumor substance can be isolated from colostrum, making the art unpredictable and necessitating more disclosure in the specification. Applicant points out the claims are amended to encompass only anti-tumor antibodies isolated from colostrum. As discussed above, the art related to the isolation of antibodies from complex biological fluids, including colostrum, is well developed and highly predictable. Applicant also provides guidance with respect to the anti-tumor properties of the isolated antibody by making reference to his prior published PCT application WO 02/07739 and Hungarian patent application P0002597 (see page 3, line 13, referring to the prior applications cited at page 1, lines 12 and 19. Thus, the art as related to the currently amended claims is highly predictable and favors enablement.

6) Amount of Direction or Guidance Provided: The Examiner asserts that the Applicant has provided insufficient guidance for practicing the claimed method because it is unclear what constitutes “the rest” in claim 4, step d) and that the purpose for performing other steps of the claimed method is unclear. When viewed in context, it is clear that “the rest” constitutes the solid matter pellet that results from the centrifugation process of step c). The specification is

clear that the aqueous upper and medial layers are separated and retained and the organic layer is discarded (“spilled”). Specification at page 3, lines 28-31. During centrifugation, the solid (insoluble) matter forms a pellet in the bottom of the vessel and is the only remaining component which constitutes “the rest”. The claims are amended herein to clarify that the solid material is separated in step d) and to clarify the subsequent processes that are performed using the pellet.

Generally, with respect to this Wands factor, the specification provides a highly detailed method for isolating the desired antibody from colostrum. Many of the specific features of the disclosed method are required for the claimed invention. At page 3, lines 12-21 of the specification, Applicant discloses that the antibody isolated by this method had the expected biological activity. Thus, relative to the claims, the specification provides a high level of direction which favors enablement.

7) The Presence or Absence of Working Examples: As the Examiner notes, the specification provides a working example that falls within the scope of the claimed method. This constitutes a working example and favors enablement.

8) The Quantity of Experimentation Necessary: In view of the narrow claim scope and their high level of concordance with the working examples in the specification, no significant quantity of experimentation is required to successfully practice the claimed invention. This factor, therefore, favors enablement.

Applicant respectfully submits that each and every Wands factor favors a ruling that the specification, along with the relevant and cited prior art, adequately enables the claimed method. Applying the correct legal framework of a balancing test makes such a ruling imperative. Thus, for the foregoing reasons, Applicant urges that the current claims are enabled and that this rejection should be withdrawn.

**Rejection under 35 U.S.C. § 112, second paragraph**

Claims 4 and 25 stand rejected for indefiniteness. This paper makes amendments to clarify that the upper layer is separated from the medial layer which can optionally be recombined later. The claims are also amended to make clear the procedure for further processing the pellet obtained in step c) of claim 4. In view of the current amendments, these rejections may be withdrawn.

**CONCLUSION**

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

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